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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,362

06/26/2003

Patrick Miles

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JONATHAN SPANGLER  
NU VASIVE, INC.  
4545 TOWNE CENTRE COURT  
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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

05/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/608,362	<b>Applicant(s)</b> MILES ET AL.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-14 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-14 and 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/29/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-14, 19-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 7,207,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 5-14, 19-27 are to be found in claims 1-38. The difference between claims of the application and claims of the patent lies in the fact that the patent claims include many more elements and are thus much more specific. Thus the invention of claims of the patent is in effect a "species" of the "generic" invention of claims of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by the claims of the patent. They are not patentably distinct.

Claims 5-14, 19-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5,6,8,12-15,20,22-26,29,30,33-42 of copending Application No. 10/444,917. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 5-14, 19-27 are to be found in claims 5,6,8,12-15,20,22-26,29,30,33-42 of the co-pending application. The difference between claims of this application and claims of the co-pending application lies in the fact that the co-pending application's claims include many more elements and are thus much more specific. Thus the invention of claims of the co-pending application is in effect a "species" of the "generic" invention of claims of the application. It has been held that the generic invention is "anticipated" by the "species". See *in re Goodman*, 29 USPQ2d 2010 (Fed. Clr. 1993). Since claims of the application are anticipated by the claims of the co-pending application. They are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-12,14, 19-27 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jacobson (4,545,374) in view of Griffith et al. (6,325,764) in view of Wilder (4,562,832) in view of Prass (6,306,100).

Jacobson discloses a system for accessing a surgical target site comprising an initial distraction system (21,24) for creating an initial distraction corridor, wherein the initial distraction system includes a K-wire (24) an assembly (11) capable of distracting from the initial distraction corridor to a secondary distraction corridor (21) and adapted to establish the operative corridor via a lateral, trans-psoas approach; as best seen in FIG.20.

It is noted that Jacobson did not teach of a plurality of blades for retracting from the secondary distraction corridor to thereby create an operative corridor to the surgical target site; as claimed by applicant. However, in similar art, Wilder et al evidences the use of a plurality of blades to further distract the target site.

Therefore, given the teaching of Wilder et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Jacobson , as taught by Wilder et al to further distract the target site.

It is also noted that the above combination of references did not teach of a system including at least one simulation electrode; as claimed by applicant. However, in similar art, Griffith et al provides the evidence of the use of a distraction system including at least one electrode to prevent nerve damage during surgery.

Therefore, given the teaching of Griffith et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Jacobson/Wilder, as taught by Griffith et al to prevent nerve damage during surgery.

It is al noted that the above combination of references did not teach of a control unit that is capable of sensing and EMG response of a muscle associated with a nerve depolarized by stimulation, and communicating at least one of a visual and audio communication a user indicia representing at least one of the nerve proximity and the nerve direction; as claimed by applicant. However, in a similar art, Prass provides the evidence of a nerve stimulation system and further provides a control unit that is capable of sensing an EMG response of a muscle associated with a nerve depolarized by stimulation, determining a stimulation threshold required to obtain the EMG response, and communicating at least one visual indicia and audio communications a user indicia representing at least one of the nerve proximity and the nerve direction to a user and a display operable to display at least the responses to a user (column 19, lines 56-64, column 41, lines 20-28, column 42, lines 33-38).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination as set forth above to include the use of a control unit for determining a stimulation threshold and a means for communicating data to a user, as taught by Prass to provide a means of accurately quantifying a determined audio-visual response.

Claim 13 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Jacobson (4,545,374) in view of Griffith et al. (6,325,764) in view of Wilder (4,562,832) in view of Prass (6,306,100) in view of Cohen et al. (2002/0161415).

It is noted that the above combination of reference did not teach of a touch-screen display operable to receive commands from a user, as claimed by applicant. However, in similar art, Cohen et al provide the evidence of the use of a nerve simulation system and further teach of a touch-screen display operable to receive commands from a user.

Therefore, given the teaching of Cohen et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of the combination above to include the use of a display with a touch screen to provide a user with a means for inputting data to the system.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

3,682,162                      Coyler                      600/554

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/  
Primary Examiner, Art Unit 3733  
May 5, 2008